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K103745

JUL 20 2011

5. 510(k) Summary

1. SUBMITTER INFORMATION

Name:	GlaxoSmithKline Consumer Healthcare
Address:	1500 Littleton Road Parsippany, NJ 07054-3884
Contact Person:	Wendy A. McManus
Telephone/Fax:	973-889-4415 973-889-2501 (fax)
Date Summary Prepared:	December 21, 2010

2. DEVICE NAME

Device Name:	Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief
Trade or Proprietary Name:	Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief
Common or Usual Name:	Saliva, Artificial
Classification Name (if known):	Saliva, Artificial

3. IDENTIFICATION OF EQUIVALENCE

Laclede, Inc.	*Oral Balance Gel* cleared in (K061331)
Laclede, Inc.	*Oral Balance Liquid* cleared in (K061331)

4. DEVICE DESCRIPTION

Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief is a specially formulated artificial saliva substitute which contains moisturizers, humectants, a protein, and patented salivary enzymes that collectively have lubricating, moisturizing, soothing, and refreshing properties to relieve & treat the symptoms of

K103745

Dry Mouth. The spray is supplied in a 1.5 oz. non-pressurized pump action spray bottle fitted with cap.

5. STATEMENT OF INTENDED USE

Relieves and treats the symptoms of dry mouth; refreshes mouth odors, soothes oral irritations, moisturizes, lubricates, and diminishes dry discomfort.
Indication for Use: Relieves the symptoms of dry mouth; refreshes, moisturizes, soothes oral irritation, and lubricates oral dryness.

6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

Characteristics of the device compared to the predicate devices.
Substantial Equivalence Comparison Chart

PRODUCT:	***Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief (Proposed Device)***		***Biotene Oral Balance Gel (Predicate 1)***	***Biotene Oral Balance Liquid (Predicate 2)***
INTENDED USE	Symptomatic Treatment of Xerostomia		Symptomatic Treatment of Xerostomia	Symptomatic Treatment of Xerostomia
METHOD OF USE	Ready to use spray		Ready to use gel	Ready to use liquid
APPLICATIONS PER DAY	As needed		As needed	As needed
DISEASE STATE	Xerostomia		Xerostomia	Xerostomia
AREA OF USE	Oral Cavity		Oral Cavity	Oral Cavity
TYPE OF PRODUCT	Liquid		Gel	Liquid
PRESENTATION	Non-sterile		Non-sterile	Non-sterile

7. Discussion and conclusions from the nonclinical and clinical tests

Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief has been shown in nonclinical studies to be safe (Toxicology Assessment) and stable (Stability Study) for its intended use. It has also been shown to be effective (Use Study).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Wendy A. McManus
Regulatory Associate, US Regulatory Affairs
Glaxosmithkline Consumer Healthcare (GSKCH)
1500 Littleton Road
Parsippany, New Jersey 07054

JUL 20 2011

Re: K103745
Trade/Device Name: Biotene Moisturizing Mouth Spray for Dry Mouth Symptom Relief
Regulation Number: None
Regulation Name: Cavity Varnish
Regulatory Class: Unclassified
Product Code: LFD
Dated: May 24, 2011
Received: June 1, 2011

Dear Ms. McManus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/C entersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.

Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103745

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4. Indications for Use Statement

510(k) Number (if known): N/A

Device Name: Biotène Moisturizing Mouth Spray for Dry Mouth Symptom Relief

Indications for Use:

Relieves the symptoms of dry mouth; refreshes, moisturizes, soothes oral irritation, and lubricates oral dryness.

(PLEASE DO NOT WRITE BELOW THIS LINE, CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Officers of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over-The-Counter Use** ___X____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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